

April 18, 2001

Elmer Rauckman, Ph.D.
Dioxolane HPV Consortium
One Rowlands Road
Flemington, NJ 08822

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dioxolane (CAS No. 646-06-0), posted by EPA on December 19, 2000. I commend the Dioxolane Manufacturer's Consortium for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The Consortium has prepared an excellent hazard profile. The Consortium only needs to supply the assumptions and data inputs for transport/distribution modeling. As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA notes that the Consortium included statements in its submission about the exposure and risk potential of dioxolane. The focus of the Challenge program is hazard screening and is not intended to be a venue for discussing or evaluating risk, hence, we have not considered this information in our review of the test plan.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that the Consortium advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submissions and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
C. Auer
M. E. Weber
A. Abramson

EPA Comments on Chemical RTK HPV Challenge Submission:

Dioxolane

SUMMARY OF EPA COMMENTS

The sponsor, The Dioxolane Consortium, submitted a Test Plan and Robust Summaries to EPA, dated November 20, 2000, for Dioxolane (CAS # 646-06-0). EPA posted the submission on the RTK HPV Challenge Web site on December 19, 2000.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. Robust summaries are adequate, except that for the fugacity model, the sponsor needs to provide the assumption and data inputs to the model (see Guidance for Robust Summary preparation).
2. Health Endpoints: All appropriate SIDS-level tests have been performed and adequate robust summaries have been submitted.
3. Ecotoxicity. The robust summaries for fish, algae, and invertebrate studies are adequate for the purposes of the U.S. HPV Challenge Program.

EPA is requesting that the Sponsor advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE DIOXOLANE CHALLENGE SUBMISSION

General

The Consortium has prepared an excellent hazard profile.

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

Adequate existing data are available for these endpoints.

Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

Adequate existing data are available for these endpoints.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate existing data are available for these endpoints.

Ecological Effects (fish, daphnid, and algal toxicity)

Adequate existing data are available for these endpoints.

SPECIFIC COMMENTS ON ROBUST SUMMARIES

Fate

For the fugacity model, the sponsor needs to provide the assumption and data inputs to the model (see Guidance for Robust Summary preparation).

EPA recommends using the EQC Level III model from the Canadian Environment Modeling Centre at Trent University, which allows full control of data inputs. This model can be found at the following Web address: <http://www.trentu.ca/academic/aminss/envmodel/>.

Followup Activity

EPA requests that the Sponsor advise the Agency within 60 days of any modifications to its submission.